REMARKS

Applicants have carefully considered this Application in connection with the Examiner's Office Action, and respectfully request reconsideration of this Application in view of the above amendments and the following remarks.

Claims 1-7, and 11-47 are pending in this application.

I. CLAIM REJECTIONS UNDER 35 USC §112

Claims 1-7, and 29-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner states that the term "substantially free from a core-shell polymer configuration" is not supported in the specification.

Applicants respectfully submit that the term "substantially free from a core-shell polymer configuration" is supported in the original Claim 1 and in paragraphs [0006], [0011], [0012], [0013], [0014] of the specification.

The claims are clearly directed to a composition which has an interpenetrating polymer network structure ("IPN"). The fact that the composition described has an IPN structure necessarily means that the nanoparticles are substantially free from core-shell configuration. A nanoparticle which possessed core-shell configuration would exhibit a lack of interpenetration between the polymer networks, thereby forming a core and a shell.

Moreover, the term "substantially free from core-shell configuration" was explicitly recited in original Claim 1 as filed.

This concept is further demonstrated by the teaching in paragraph [0011] that, "These nanoparticles have a first polymer interpenetrating a second polymer forming an interpenetrating polymer network ("IPN")." It is also clear from paragraph [0012], which teaches that, "A second aspect of the current invention pertains to a method of preparing an interpenetrating polymer network."

Therefore, Applicants respectfully submit that the term "substantially free from core-shell configuration is supported in the specification, and request that the rejection be withdrawn.

II. CLAIM REJECTIONS UNDER 35 USC §103

A. Claims 1-9 and 11-28 over Jones in view of Gan, in further view of Kurisawa, in further view of Cai

The Examiner has rejected Claims 1-9 and 11-28 under 35 U.S.C. 103(a) as being unpatentable over Jones et al. *Macromolecules*, 2000, Vol. 33, p. 8301-8306 ("the Jones Reference"), in view of J Am. Chem. Soc., 2001, Vol. 123, p. 7511-7517 ("the Gan Reference"), in view of Kurisawa et al. *Journal of Controlled Release*, 1998, Vol. 54, p. 191-200 ("the Kurisawa Reference") and further in view of over Cai et al. *Journal of Applied Polymer Science*, 2002, Vol. 83, p.169-178 ("the Cai Reference").

Applicants respectfully disagree with the Examiner's assessment. The Jones Reference teaches a core-shell nanoparticle (Title; abstract; p. 8301, column 2, third paragraph; p. 8302, column 1, sixth paragraph; Figures 1, 2, 4, 5, and 6; Scheme 1; and p. 8305, column 1, last paragraph). The nanoparticles of the Jones Reference have a distinct core phase, and a distinct shell phase, with an interface between the two. Please see Figure 1, on page 8302, of the Jones Reference. The Jones Reference teaches, "(t)hese images also suggest that the interface between the two materials is fairly sharp and not highly interpenetrated." (p. 8302, column 1, sixth paragraph). This is a fundamentally different type of particle from an IPN nanoparticle, as described in detail above. In fact, any give nanoparticle can only be a core-shell nanoparticle (wherein the polymer networks do not interpenetrate) or an interpenetrating polymer network nanoparticle, but not both. An IPN nanoparticle is composed of uniformly interpenetrating polymer networks over the entire particle volume.

The Examiner argues that the Gan Reference suggests adjusting the temperature of polymerization, since P-NIPA is poorly soluble in water above the LCST, and that this could have been applied to the method of the Jones Reference to result in the currently claimed composition.

However, while the Examiner suggests that changing the temperature of polymerization in the method of the Jones Reference might change the particle size of the aqueous dispersion, it would not have produced interpenetrating polymer network nanoparticles. The method of the Jones Reference would still produce core-shell nanoparticles, which are distinct from the nanoparticles of the current claims.

Simply changing the concentrations of the polymer core would not produce uniform IPN nanoparticles. The key point is not to reduce polymer concentration or temperature, but to change the interaction between the first polymer network and the second polymer network. In the currently-claimed invention, the IPN nanoparticles are formed at approximately 21°C. This is because the inventors have determined that this temperature is lower than the LCST of the first network, and as a result the first network and the second network are both hydrophilic so that they can form uniformly distributed IPN nanoparticles.

Moreover, the gelation temperature is a unique property of the currently-claimed IPN nanoparticles. Below the gelation temperatures, the IPN nanoparticles disperse in water, and the entire system is fluid. Above the gelation temperature, the IPN nanoparticles stick together and the entire dispersion becomes a large gel. In contrast, the core-shell nanoparticles of the Jones Reference always disperse in water regardless of temperature. The aqueous dispersion of core-shell nanoparticles is always a fluid. Therefore, there is no gelation temperature in the Jones Reference.

The Kurisawa Reference teaches a method for adding a drug to a bulk gel, but does not provide interpenetrating polymer network nanoparticles. The bulk gel of the Kurisawa Reference is a single piece of large gel, and does not exhibit a gelation temperature as the currently-claimed nanoparticles do. The bulk gel of the Kurisawa Reference has nothing to do with nanoparticle sticking to one another or not sticking to one another.

The Cai Reference teaches microgels entrapped in a bulk gel, which is distinct from the uniformly interpenetrating polymer network nanoparticles of the current claims. These structurally different particles would not have motivated a person of skill in the art to produce the uniformly interpenetrating polymer network nanoparticles of the current claims.

Therefore, because none of the cited references exhibits the gelation properties of the currently-claimed composition, and because the references do not suggest modifications which would lead to the formation of a truly uniformly interpenetrating polymer network nanoparticle, the references would not motivate a person of skill in the art to practice the currently-claimed invention.

B. Claims 29-47 over Jones in view of Cai, in further view of Hennink & Nostrum

The Examiner has rejected Claims 29-47 over the Jones Reference, in view of the Cai Reference, and in further view of Hennink and Nostrum *Advanced Drug Delivery Reviews*, 2002, Vol. 54, p. 13-36 ("the Hennink Reference").

Applicants respectfully disagree. As described in detail above, the Jones Reference does not teach providing a dispersion of IPN nanoparticles. Instead, the Jones Reference teaches core-shell nanoparticles, which are entirely distinct compositions.

Similarly, the Cai Reference does not teach IPN nanoparticles, but rather bulk hydrogels. These bulk hydrogels do not have the property of gelation which is exhibited by the currently-claimed composition, as described in detail above.

The Hennink Reference teaches cross-linking agents, but does not teach a method for producing IPN nanoparticles.

Therefore, since none of the cited references teaches IPN nanoparticles, none of the references could have taught or suggested the currently-claimed method for making IPN nanoparticles.

III. Conclusion

Applicants respectfully submit that, in light of the foregoing comments and amendments, all pending claims are now in condition for allowance. A Notice of Allowance is therefore requested.

If the Examiner has any other matters which pertain to this Application, the Examiner is encouraged to contact the undersigned to resolve these matters by Examiner's Amendment where possible.

Respectfully submitted,

T. Ling Chwang
Reg. No. 33,590
Jackson Walker L.L.P.
901 Main Street, Suite 6000
Dallas, Texas 75202
Tel: (214) 953-5959
Fax: (214) 661-6870

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